REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 28, 2007 (hereinafter Office Action) have been considered. Claims 1-68 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The Applicant acknowledges the Examiner's remarks regarding the restriction requirement. The Applicant reserves the right to continue to contest the propriety of the restriction requirement, whether by petition or other appropriate means.

Claims 1-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,074,301 to *Gill* (hereinafter "*Gill*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Gill* does not teach each and every element of independent claim 1, and therefore fails to anticipate this claim.

The Applicant's independent claim 1 recites, among other features, control circuitry provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of the tachyarrhythmia therapy in response to detection of a tachyarrhythmia requiring treatment and delivery of the non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole.

Gill discloses an implantable medical device to detect ventricular tachycardia and ventricular fibrillation and "deliver therapy in the form of electrical energy to cardiac tissue to revert tachycardia and restore sinus rhythm." (Col. 1, Lines 8-12). *Gill* acknowledges that the heart may be stopped after delivery of cardioversion therapy. (Col. 6, Lines 34-37; Fig. 4C). Therefore, *Gill's* device delivers bradycardia pacing therapy after the delivery of cardioversion therapy and detection of asystole as part of *Gill's* therapy regime to restore

sinus rhythm. (Col. 6, Lines 34-39; Fig. 4C). The Applicant respectfully submits that *Gill's* teaching of delivering bradycardia pacing to treat asystole does not constitute an anticipatory teaching of a non-physiologic, life sustaining pacing therapy.

Bradycardia pacing therapy, as understood by one having ordinary skill in the art, paces a heart faster than the intrinsic rate to increase cardiac output and support physiologic function of a patient. For example, although *Gill* does not explicitly define bradycardia pacing, *Gill* does discuss "a bradycardia support system as well as a high energy shock system to revert ventricular tachycardia to normal sinus rhythm." (Col. 1, Line 68 – Col. 2, Line 2; emphasis added). *Gill's* invention delivers a high energy shock followed by bradycardia pacing to restore sinus rhythm. (Col. 1, Lines 9-12; Fig. 4C).

As quoted in MPEP § 2131, "the identical invention must be shown in as complete detail as is contained in the ... claim." (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). The Applicant respectfully submits that *Gill* does not disclose delivery of a non-physiologic, life sustaining pacing therapy, as recited in independent claim 1. Nothing from *Gill's* disclosure teaches that *Gill's* bradycardia pacing is anything but conventional bradycardia pacing that supports cardiac output to restore physiologic function.

Furthermore, not only does *Gill* fail to disclose a non-physiologic, life sustaining pacing therapy, but *Gill's* disclosure of a bradycardia therapy diverges from a teaching of a non-physiologic, life sustaining pacing therapy, such that the two therapies would be understood to be materially different by one having ordinary skill in the art.

For example, the differences between a non-physiologic, life sustaining pacing therapy and bradycardia pacing therapy are highlighted by the Specification as follows:

> An implantable cardiac device of the present invention finds particular utility in the context of preventing sudden cardiac death (SCD) in patients that may not require a traditional implantable cardiac defibrillator (ICD). Although ICDs are very effective at preventing SCD, most people at risk of SCD are not provided with implantable defibrillators. Many people that are at risk of SCD, for example, may not have a history of arrhythmias or other comorbidities that are often considered threshold factors that must be present before a person can receive an ICD. The high costs of conventional ICDs (device and surgical implant costs),

and the relatively stringent requirements that a candidate patient must satisfy in order to justify the risks and costs of conventional ICD implantation, may also significantly limit the number of patients that can receive a conventional ICD. Other reasons why people at risk of SCD do not receive conventional ICDs, particularly those that have a cardiac pacing capability, include the limited number of physicians qualified to perform lead/electrode implantation and pacing threshold determinations, and a limited number of surgical facilities adequately equipped to accommodate such cardiac device implant procedures. Each year, SCD claims the lives of some 300,000 Americans—with 80% to 90% of those deaths caused by ventricular fibrillation.

It is believed that an implantable cardiac device of the present invention may be appropriate for implantation in a significantly larger patient population than that for which conventional ICDs are appropriate.
[Page 7, Line 10 – Page 8, Line 3]

. . .

Embodiments of the present invention are directed to maintaining circulatory support by providing post-shock pacing pulses from an SCDP device. Embodiments of the present invention are directed to post-shock asystole prevention using post-shock pacing therapies. According to one approach, and in contrast to conventional bradycardia pacing modalities, normal heart rate is not maintained by the SCDP device. Rather, a single pacing pulse is delivered after a predetermined interval following detection of the last R-wave or delivery of a pace pulse (i.e., asystole detection). Delivery of post-shock pacing pulses is terminated once the heart is able to beat on its.
[Page 28, Lines 15-23; emphasis added]

Furthermore, the Applicant's Specification identifies a "non-physiologic, life sustaining pacing therapy" as pacing at a rate lower than bradycardia pacing. ("[i]n an embodiment in which asystole prevention pacing is also made available, the SCDP device 502 produces pacing pulses in accordance with a non-physiologic, life sustaining pacing therapy, such as pacing therapy deliverable at a rate lower than a bradycardia pacing rate." Specification, Page 20, Lines 15-18).

When referencing the quotation of the immediately above passage in the previously filed Office Action response, the Examiner warned that unclaimed limitations from the Specification are not read into the claims. (Office Action, Page 2).

The passage was quoted to illustrate that a non-physiological, life sustaining therapy is different from bradycardia therapy. The Applicant respectfully submits that referencing the Specification to understand claim terms is well known as an acceptable means to

highlight difference between the claims and prior art. (See *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)). Identifying portions of the Specification to show that bradycardia therapy and a non-physiologic, life sustaining pacing therapy diverge in at least their respective pacing rates is not improperly importing a limitation into the Specification. Moreover, the independent claims already recite "non-physiologic," and as such the Applicant is not importing limitations into the claims.

The Applicant respectfully submits that the Applicant's claimed invention and *Gill's* conventional bradycardia therapy device address different problems with materially different therapies. This distinction illustrates that *Gill's* bradycardia pacing therapy and the Applicant's non-physiologic, life sustaining pacing therapy are clearly different therapies, and that *Gill's* bradycardia pacing therapy does not anticipate a non-physiologic, life sustaining pacing therapy, as recited in independent claim 1.

Moreover, the Office Action has recognized differences in therapies that clearly require recognition that bradycardia pacing and a non-physiologic, life sustaining pacing therapy are materially different. For example, when addressing the restriction requirement, the Office Action states that the "non-physiologic, life sustaining pacing therapy" of claim 1 is a "different therapy strategy, in response to a different, more specific cardiac condition than" the "pacing therapy deliverable at a rate lower than a bradycardia pacing rate" of claim 16. (Office Action, Page 3). The above statement was made in the Office Action even though the Applicant pointed out on page 14 of the prior response that the Specification states that a pacing therapy deliverable at a rate lower than a bradycardia pacing rate is a non-physiologic, life sustaining pacing therapy.

Therefore, the sustaining rational for the restriction recognized a difference between a non-physiologic, life sustaining pacing therapy and a pacing therapy deliverable at a rate lower than a bradycardia pacing rate that makes the two therapies recognizable as different therapies. Even if there is a difference between those two therapies, the difference is small, particularly in comparison to the far greater differences between *Gill's* bradycardia therapy and a non-physiologic, life sustaining pacing therapy of claim 1. As such, the sustaining rational for the restriction requirement demands that *Gill's* bradycardia therapy and a non-

physiologic, life sustaining pacing therapy of claim 1 be recognized as materially different therapies.

Furthermore, the Applicant respectfully submits that sufficient consideration was not given to some claim terms of independent claim 1. For example, in addressing the rejection of claim 1, the Office Action mailed October 6, 2006 (referenced in the current Office Action on page 4) states that:

> A defibrillation shock (col. 6, lines 34-44; Figure 4C) 'which has succeeded in reverting the VY/VF, asystole is selected and thus bradycardia pacing is commenced, about 4 seconds after the delivery of the defibrillation shock. By this time, the pro-arrhythmic effect of a premature recommencement of bradycardia support pacing immediately post reversion has been avoided, as there has been sufficient time for the patient's heart's conduction system to become reorganized and susceptible to bradycardia support pacing.' The examiner considers this to be energy delivery circuitry that is capable of delivering a non-physiological, life sustaining pacing therapy in response to detection of cardiac asystole.
>
> (Page 4; emphasis added).

The Applicant's claim 1 recites "control circuitry provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of . . . non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole." Regardless of whether *Gill's* energy delivery circuitry can deliver a non-physiological, life sustaining pacing therapy, *Gill* does not disclose control circuitry configured to coordinate delivery of a non-physiologic, life sustaining pacing therapy.

It is well established that control circuitry, such as circuitry that includes a controller that carries out instructions, such as an energy delivery protocol, defines a physically (i.e., structurally) new device. For example, as is discussed in *WMS Gaming, Inc. v. Int'l Game Technology*, 184 F.3d 1339, 1348 (Fed. Cir. 1999):

> A general purpose computer, or microprocessor, programmed to carry out an algorithm creates "a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software." *In re Alappat,* 33 F.3d 1526, 1545, 31 USPQ2d 1545, 1558 (Fed.Cir.1994) (en banc); *see In re Bernhart,* 57 C.C.P.A. 737, 417 F.2d 1395, 1399-1400, 163 USPQ 611, 615-16 (CCPA 1969) ("[I]f

a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged."). The instructions of the software program that carry out the algorithm electrically change the general purpose computer by creating electrical paths within the device. These electrical paths create a special purpose machine for carrying out the particular algorithm.

Moreover, assuming, *arguendo*, that the therapy features of claim 1 were not considered "structural" limitations, it is well established that any "functional" language in the claims must be given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language." (*Ex parte Bylund*, 217 U.S.P.Q. 492, 498 (Bd. Pat. App. 1981); *See also, In re Venezia*, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976) and MPEP 2173.05(g)).

As such, the Applicant respectfully submits that it even if *Gill's* energy delivery circuitry is capable of delivering a particular pacing therapy, *Gill* does not provide a teaching that can account for the Applicant's claimed control circuitry configured to coordinate delivery of a non-physiologic, life sustaining pacing therapy of claim 1.

For each of the reasons discussed above, the Applicant respectfully submits that claim 1 recites features that must be given patentable weight and, when properly given such, clearly distinguish the elements and limitations of independent claim 1 from *Gill's* disclosure.

Dependent claims 2-12, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Gill*. While the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-12 are also not anticipated by *Gill*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1-12 as being anticipated by *Gill* is not sustainable.

Claims 13-15 and 68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Gill.*

The Applicant's claim 68 recites "wherein the non-physiologic, life sustaining pacing therapy comprises delivery of pacing pulses at a rate between 5-20 pulses per minute." In addressing claim 68, the Office Action states that "it would have been obvious to one having ordinary skill in the art at the time of invention was made to deliver pacing pulses at a rate of 5-20 pulses per minute, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233." (Page 4).

The Applicant's Specification states that:

> Embodiments of the present invention are directed to maintaining circulatory support by providing post-shock pacing pulses from an SCDP device. Embodiments of the present invention are directed to post-shock asystole prevention using post-shock pacing therapies. According to one approach, and in contrast to conventional bradycardia pacing modalities, normal heart rate is not maintained by the SCDP device. . . Pacing, in this regard, is provided only as a means to maintain patient life post shock during asystole. A suitable pacing rate typically ranges between 2 and 40 pulses per minute (ppm), with 5-20 ppm representing a typical pacing rate.
>
> (Page 28, Lines 15 – Page 29, Line 12)

The Applicant respectfully submits that, particularly in light of the above passage, a pacing rate of 5-20 ppm is not merely an optimization or a workable range in light of *Gill's* bradycardia pacing therapy. Rather, as discussed above, the claimed therapy is materially different from *Gill's* bradycardia therapy. Accordingly, a non-physiologic, life sustaining pacing therapy with a pacing rate between 5-20 ppm is not a mere optimization or a workable range of a prior art disclosure, but rather is a more particularized recitation of a therapy deliverable by an already patentable apparatus.

Each of claims 13-15 and 68 depend from independent claim 1. Independent claim 1 is not obvious for at least the reason that *Gill* fails to teach or suggest each and every limitation recited in independent claim 1. Furthermore, while the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim

1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 13-15 and 68 are not made obvious by *Gill*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 13-15 and 68 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious matter of design choice, or known in the art. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.119PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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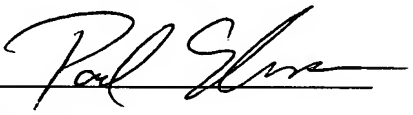
By: 

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